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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/621,725 03/21/96 LEHMANN

P CASE-02138

HM22/0613

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EXAMINER

SCHWADRON, R

ART UNIT

PAPER NUMBER

1644

32

DATE MAILED:

06/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/621,725

Applicant(s)

Lehmann et al.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 11/27/2000

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 2, 4-8, 18, 20-25 is/are pending in the application.

4a) Of the above, claim(s) 4-8, 18, 20-24 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 2, 25 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: ☐ approved ☒ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

1. In view of the Brief filed on 11/27/2000, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (a) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (b) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. Claims 1,2,25 are under consideration. The amendment filed 11/27/2000 has been entered.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Muir et al. (US Patent 5,891,435).

Muir et al. teach immunization of humans with MBP to prevent/ameliorate MS wherein the adjuvant IFA is used (see column 9, last paragraph, column 10, column 6, column 8, lines 8-12, and column 13, lines 13-15).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1,2,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir et al. (US Patent 5,891,435) in view of Gaur et al., Goodwin et al. (US Patent 5,569,585) and Oprandy (US Patent 5,200,312).

Muir et al. teach immunization of humans with MBP to prevent/ameliorate MS wherein the adjuvant IFA is used (see column 9, last paragraph, column 10, column 6, column 8, lines 8-12, and column 13, lines 13-15). Muir et al. do not teach the assay steps of claim 2. Gaur et al. teach that the in vivo response to MBP peptide administered in IFA can be measured in lymphocyte proliferation assays (see Figures 1 and 2). The response of T cells would have been alternatively measured using art known lymphokine assays, because the art recognizes that activated T cells produce lymphokines in response to antigenic stimulation (see Goodwin et al., see column 10, penultimate paragraph). ELISA assays for T cell cytokines are known in the art as is the membrane recited in claim 2 (see specification, page 8, first paragraph and Goodwin et al., column 10). Oprandy teaches the use of antibody coated PVDF membranes in immunoassays (see column 3 and Example 1). Oprandy teaches that the use of antibody coated PVDF membranes in immunoassays results in improved sensitivity (see column 3, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Muir et al. teach immunization of humans with MBP to prevent/ameliorate MS wherein the adjuvant IFA is used, Gaur et al. teach that the in vivo response to MBP peptide administered in IFA can be measured in lymphocyte proliferation assays, and the response of T cells would have been alternatively measured using art known lymphokine assays, because the art recognizes that activated T cells produce lymphokines in response to antigenic stimulation (see Goodwin et al., see column 10, penultimate paragraph), ELISA assays for T cell cytokines are known in the art and Oprandy teaches that the use of antibody coated PVDF membranes in immunoassays results in improved sensitivity. One of ordinary skill in the art would have been motivated to do the aforementioned because Gaur et al. teach that after MBP in IFA immunization, the proliferative response of T cells is tested and the response of T cells would have been alternatively measured using art known lymphokine assays, because the art recognizes that activated T cells produce lymphokines in response to antigenic stimulation. One of ordinary skill in the art would have been also been motivated to do the aforementioned because Oprandy teaches that the use of antibody coated PVDF membranes in immunoassays results in improved sensitivity.

7. No claim is allowed.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1200~~ 1600



Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
June 12, 2001